INB related interactive dialogues
Topic 1. Article 12 (Pathogen Access and Benefit-Sharing System)

Discussion questions proposed by the Bureau for resource persons

1. PABS and Nagoya Protocol related matters

If Member States reach consensus on the PABS instrument during the negotiation, including that its design is consistent with, and does not run counter to the objectives of the Convention on Biological Diversity and the Nagoya Protocol, and the INB decides that PABS can be recognized as a specialized international access and benefit-sharing instrument (SII):

1.1. Can PABS, as SII, be universally applied to all Parties to the Pandemic Agreement, i.e. both Parties and non-Parties to the Nagoya Protocol?

The precise process of defining an SII is far from clear. For the PIP Framework sone of the national guidance recognizes the framework as an ABS mechanism that does not run counter to the Nagoya Protocol (examples include the EU guidance and the UK guidance on ABS). I do not know if the CBD can stipulate that the PABS is an SII for all parties.

1.2. What criteria and/or mechanism(s) are to be used for the recognition of PABS as a SII?

- For Parties to CBD and the Nagoya Protocol who are Parties to the Pandemic Agreement?
- For non-Parties to CBD and the Nagoya Protocol who are Parties to the Pandemic Agreement?
- What domestic legal arrangements are needed, such as amendment of national ABS laws, to recognize PABS and ensure that PABS materials are not subject to additional or different PIC and MAT ?

From experience with the PIP FW, it seems as if guidance needs to be national for recognizing an SII. This is a matter of debate in the CBD and seems that reaching a conclusion has been postponed (see https://www.cbd.int/doc/decisions/np-mop-04/np-mop-04-dec-11-en.pdf).

1.3. During the INB negotiations, what are the considerations that should guide the INB so as to maintain coherence between the future PABS and the Nagoya Protocol?

A reasonable model might be the PIP FW and the voluntary contributions. However, the utilization of the funds collected needs to ensure that there is equitable use of the funds should direct funding be required. How the monies/contributions are collected also needs to be equitable.

The scope of the Nagoya Protocol and ABS also needs to be considered carefully. The EU guidance document goes into considerable detail. Here the PABS might need to align with the understanding of 'utilization' of a genetic resource in national guidance documents.

1.4. Are there any specific issues in the PABS under ongoing INB negotiations that may prejudge the ongoing discussions on the handling of DSI within the CBD and the Nagoya Protocol?

The handling of DSI (for example gene sequence data) seems to be in a matter of flux. It is essential that the PABS is compatible with possible future decisions of the CBD and the outcomes of COPs

and MOPs. It seems inevitable that GSD will be treated as an analogous fashion to genetic resources. Here though tangible transfers of GSD is not as easily tracked as the sharing of physical resources. End-product tracking might be an option, but that fails to cover all the concepts of utilization as described in some of the national guidance and so might be deemed as running counter to the guidance.

1.5. In principle a non-Party to PABS who is a Party to the Nagoya Protocol could view that PABS is not 'consistent with and not run counter to the objectives of the CBD and the NP'. In this case, is the non-Partiy to PABS that is affected by the conclusion of a SII entitled to dispute settlement under Article 27 of the CBD?

It would seem likely.

1.6. What are elements or designs of PABS that would be inconsistent with and run counter to the objectives of the CBD and the Nagoya Protocol?

If the PABS does not cover aspects of utilization as described in the guidance on ABS (e.g. that of the EU) then there is not full alignment of the PABS and the implementation of Nagoya. On the other hand, if the PABS goes beyond the requirements of other national guidance, then this might not align. It might be that each bit of guidance could need to be updated to say that PABS does not run counter to their implementation of ABS under the CBD.

2. Issues related to access to PABS materials and sequence information

2.1. What are the current most up-to-date progresses in CBD on definition and scope of digital sequence data (DSI)? Will the current negotiated text using "sequence information" contradict/hamper the ongoing negotiation of the CBD?

I am aware that there is progress in the offing, but I am not sure how far it has got.

2.2. What are the effective technical or operational measures to ensure all users (primary users and secondary users shared by primary users) of materials and sequence information account to benefit sharing arise from the use of them?

The ABS ought to be of a similar nature to those of sharing tangible genetic resources. The tracking of sequence sharing will be very difficult. Many users will not be aware of the interpretation that government's guidance might require. If the requirements are very different for GSD from tangible samples then the system will seem to be inequitable.

2.3. What are the effective "traceability" measures which ensure users of materials and sequence information account to benefit sharing obligations?

For GSD this is very difficult. Individuals can easily avoid any data access agreements (DAAs) by direct sharing digital data with those who have not accessed the data and so are not traceable.

3. Issues related to benefit sharing

3.1. What are the positive or negative consequences to manufacturers should a PABS system be established in which there are a legally binding benefit sharing requirements to allocate certain percentage of vaccines, therapeutics and diagnostics (VTD) on a free-of-charge basis and at not-for-profit prices, as well as annual monetary contribution?

The positive aspect of this will be (as in the PIP FW) that there is a source of some levels of vaccine that will be made available as a pandemic response, and the contribution can be used to keep the channels for this open.

A negative aspect of this is which companies might up and what their relative contributions might be. In addition, should vaccine be donated internationally, the vaccine must be used in the country to which it was donated. There is not a good experience with this during SARS-CoV-2. If vaccines are not used they will not be donated. How can WHO ensure that donated vaccines are put to best use?

Would the manufacturers and commercial users of materials and sequence information consider not using the PABS system because of this required contribution?

If there was a reasonable arrangement that was equitable for manufacturers then they might be very willing to take part. However, there are likely to be ways around this though local arrangements between manufacturers and sub-national laboratories. It may well be less onerous for small start-up companies to avoid PABS, and the extra legal obligations.

3.2. If not a PABS system, are there other options which could facilitate rapid and timely sharing of materials and sequence information, and on an equal footing, sharing of monetary and non-monetary benefits arising from the use of materials and sequence information, and incentivize greater manufacturer participation? Would any of these options be preferable to a PABS system?

There seems that some kind of ABS option is needed. This is required by member states that are signatories to the Nagoya Protocol of the CBD, and have passed legislation to implement the protocol.

Key is rapid sharing in the event of a pandemic or an emerging epidemic. Bilateral agreements for ABS might well be very time-consuming and so might limit the ability to respond. The Nagoya Protocol has some flexibility, although undefined, in a public health emergency. The EU guidance does not define any flexibility. The PIP FW allows some flexibility in an emergency.

To facilitate timely sharing of resources and GSD some element of flexible timelines should be incorporated into any PABS.

3.3. What would be appropriate and sufficient triggers for such benefit sharing under a PABS system?

There needs to be pandemic preparedness – like the PIP Framework. A pre-pandemic aspect of the agreement needs to be in place.

3.4. Should benefit sharing of VTDs cover: a) PHEIC, b) pandemic emergency, c) pandemic? What would be the public health impact of each of these options?

It would seem best to have the tangible benefits that are offered to be able to be used in all public health emergencies. However, if any pandemic accord is restricted to the declaration of a pandemic then any PABS are likely to be similarly restricted.

3.5. How should the duration of the benefit sharing of VTDs be determined?

The timing of the end of benefit sharing is very difficult. There might be multiple waves of a pandemic that affect different regions differently. I expect that the length of time sharing of VTDs will have to be negotiated with the donor companies.

3.6. Is it necessary to make a reference to the Biological and Toxin Weapons Convention and, if so, what would need to be considered for the development of a PABS system that is consistent with the objectives of this Convention, in particular its article 10?

I am aware that the Biological and Toxin Weapons Convention (BTWC) has been considered for some of the pre-pandemic research that might be carried out. It is not clear to me that PABS is part of this, but this is rather to do with pre-pandemic research.

My feeling is that properly rigorous risk assessments of research carried out for pre-pandemic purposes would cover risks about which the BTWC might also have concerns. Similar problems have been raised by the European Academies' Science Advisory Council have discussed and documented their conclusions (see https://easac.eu/publications/details/gain-of-function-experimental-applications-relating-to-potentially-pandemic-pathogens) . The BTWC was not considered a body that was involed in developing research to advance medical research. The EASAC concluded "Research is usually considered to be outside the limits of the Biological Weapons Convention (BWC).

3.7. What are the differences, in terms of legal obligations of those participating in a PABS system, between two terms: a) "benefits arising from the sharing (of material and sequence information)"; and b) "benefits covered by the PABS system"?

I would need a more thorough explanation of what is meant here, with examples.

3.8. Are the expressions "benefits arising from the sharing", used in the PIP Framework, and "benefits arising from the utilization", used in the Nagoya Protocol synonymous? If not, what are the consequences of each for the PABS system?

These are not synonymous since utilization can have a much wider meaning than benefits derived from sharing. The definition of utilization is key, but if PABS is accepted as an SII in the national guidance that do not run counter to the aims of the Nagoya protocol, it is feasible that they can be treated as analogous, if not synonymous.

3.9. What are the WTO rules that should be taken into consideration, if any, in the design of a PABS system? Can Member States limit the export of VTDs that are identified as benefits arising from the PABS system, in light not only of the obligations agreed upon by parties to this system, but also of the public health goals emanating from it?

No answer: I am not familiar with WTO rules.

4. Legal issues related to the adoption of PABS system

4.1. What are the implications of adopting a PABS system under articles 19 (e.g. as a Protocol), 21 or 23 of the WHO Constitution?

Overall, WHO will recognize that its goal is to have improved health for all.

This will, in large measure, come though improvements to public health, which is driven by improved medical science. Improved medical science comes from medical research. WHO needs to ensure that medical research is not be compromised by restrictions imposed though over bureaucratic procedures.